

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEB 24 1998

Lori Malyj
Manager, Regulatory Affairs
Monsanto (Calgene Division)
1920 Fifth Street
Davis, California 95616

Dear Ms. Malyj:

This is in regard to Calgene's consultation with the Food and Drug Administration (FDA) (Center for Veterinary Medicine and Center for Food Safety and Applied Nutrition) on its insect-resistant tomato (IR) line 5345. According to Calgene, the new tomato variety has been rendered resistant to certain Lepidopteran insects through expression of the *cryIA(c)* gene from *Bacillus thuringiensis* subsp. *kurstaki*.

As part of bringing the consultation regarding this variety to closure, Calgene submitted a summary safety and nutritional assessment of the genetically modified tomato variety on December 22, 1997. This communication informed FDA of the steps taken by Calgene to ensure that this product complies with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment Calgene has conducted, it is our understanding that Calgene has concluded that the new tomato variety is not materially different in composition, safety, or any other relevant parameters from tomato lines currently on the market and that it does not raise issues that would require premarket review or approval by FDA. All materials relevant to this notification have been placed in a file designated BNF0054 that will be maintained in the Office of Premarket Approval.

Based on the information Calgene has presented, we have no further questions concerning this product at this time. However, as you are aware, it is Calgene's continued responsibility to ensure that foods marketed by the firm are safe, wholesome and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/s/

Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition

cc: HFS-200 HFS-205 HFS-206 HFS-226 HFS-235 HFS-246 HFS-247
HFS-13 HFV-200 BNF0054